

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA)
PHARMACEUTICAL COMPANY LTD.,)
TAKEDA PHARMACEUTICALS U.S.A.,)
INC., TAKEDA PHARMACEUTICALS)
INTERNATIONAL AG, and TAKEDA) C.A. No. 1-18-cv-00088-LPS
PHARMACEUTICALS AMERICA, INC.,)
Plaintiffs,) Competitively Sensitive
) Confidential Information
v.) [REDACTED]
APOTEX INC. et al.,) Public Version Filed: September 16, 2020
Defendants.)

**DEFENDANTS SANDOZ INC. AND LEK PHARMACEUTICALS D.D.'S REPLY
IN SUPPORT OF THEIR MOTION TO DISMISS
COUNTS V-VI OF PLAINTIFFS' THIRD AMENDED COMPLAINT**

Prior to Sandoz filing its motion to dismiss, Plaintiffs refused to consent to dismissal based on the untenable position that “[t]he rationale in the Court’s Memorandum Order [D.I. 813] does not apply to Plaintiffs’ declaratory judgment claim relating [to] the ’910 patent.” D.I. 839 at 1. Plaintiffs stated that they would oppose dismissal of the ’910 patent as recently as a meet-and-confer on Monday, August 31, 2020.

Plaintiffs now state that they “do not oppose Sandoz’s request that the Court dismiss Counts V and VI of Plaintiffs’ Third Amended Complaint Against Sandoz (D.I. 809) and Sandoz’s Inc.’s Ninth and Tenth Counterclaims (D.I. 845) without prejudice.” D.I. 937 at 1. Sandoz is disappointed that it had to undergo the expense of filing and briefing this motion to dismiss before Plaintiffs would consent to dismissal of these counts related to the ’910 patent. Nonetheless,

Sandoz appreciates that Plaintiffs have reconsidered their position and respectfully requests that the Court enter an order dismissing these counts without prejudice.

The only point of disagreement between the parties is the form of dismissal. Sandoz requests that the dismissal be consistent with Sandoz's proposed order (D.I. 908, Proposed Order) and the form entered with respect to the previously-dismissed polymorph patents (D.I. 814, Order), each of which simply grants Defendants' motion to dismiss without prejudice. Plaintiffs ask for an additional provision that would impose an obligation on Sandoz to provide notice if Sandoz were to ever amend its abbreviated new drug application ("ANDA") to add a new section viii statement for the '910 patent. D.I. 937 at 1–2. Plaintiffs cite no statutory or other legal authority to support this unprecedented request. Indeed, there is none. Instead, those courts that have commented on this issue have acknowledged that "[a]pplicants submitting section viii statements have no obligation to provide notice" *Purepac Pharm. Co. v. TorPharm. Inc.*, 354 F.3d 877, 880 (D.C. Cir. 2004); *Watson Labs., Inc. v. Sebelius*, No. 12-1344, 2012 U.S. Dist. LEXIS 185685, at *9 (D.D.C. Oct. 22, 2012) ("Filing a section viii statement is not an act of infringement, so it does not require applicants to provide notice to the pioneer applicant or wait thirty months for FDA approval."); *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 09-2445, 2010 U.S. Dist. LEXIS 32569, at *6 (D.N.J. Mar. 31, 2010) (quoting *Purepac*); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 345 n.7 (D.N.J. 2009) ("Section viii statements do not require notice to the patent-holder and do not allow the patent-holder to automatically initiate infringement litigation."). Thus, Sandoz has no obligation to provide notice of a section viii statement and the Court should not take the extraordinary step here of imposing such a notice obligation that has no legal basis.

For the foregoing reasons, Sandoz respectfully requests that the Court enter Sandoz's proposed form of dismissal.

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Dated: September 9, 2020

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